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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,228	05/26/2000	Pawan Seth	14577.0023US01	2041

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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/583,228
Filing Date: May 26, 2000
Appellant(s): SETH, PAWAN

Ronald A. Daignault
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 17, 2005.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because the further recitation of an intermediate coating does not constitute a distinct and patentable feature for coated medicament, claims 26-50 should stand and fall together with the rest of the claims.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

US Patent 5,378,474

Morella et al.

January 3, 1995

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 6, 9-14, 19-22, 24-50 are rejected under 35 U.S.C. 103(a) as being obvious over Morella et al.

These rejections are fully set forth in prior office action mailed September 9, 2004 and reiterated in full below.

(11) *Response to Argument*

Claims 1-4, 6, 9-14, 19-22, 24-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (USPN 5,378,474).

Morella et al. (USPN 5,378,474) teaches a substantially similar composition as those claimed herein. Morella et al. ('USPN 5,378,474) teaches a sustained release pharmaceutical composition having a core element containing an antihypertensive agent such as Verapamil Hydrochloride, binding agent, such as PVD, modified celluloses, and other well known pharmaceutical carrier and excipients; a coating comprising a methacrylic polymer (1-30% wt., soluble at a pH from 6-7.5 in the intestines), hydroxypropyl methylcellulose (4-20% wt.),

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polyethylene glycol (15-35% wt.) and a filler such as silicon dioxide (4-30% wt.), see, particularly, claims 1, 2, 7 and 9 as well as Col.4, line 24. column 11, lines 3-33. Morella et al. (USPN 5,378,474) also teaches that the active ingredient in the pharmaceutical composition reaches its maximum concentration between about 4 and about 30 hours, col. 24, claim 1 and that the bioavailability of the active agents in the pharmaceutical pellet is not compromised by food, col.7, lines 34-40. Morella discloses at least one polymer which is substantially insoluble at acidic pH (i.e., that of the stomach) but at least partially soluble at a less acidic to basic pH (i.e., the pH of the intestine), see col. 6, lines 43-52 col. 7 lines 34-62 in particular.

Morella et al. (USPN 5,378,474) does not teach the particular composition containing the specific ingredients in the amounts herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the particular composition containing the specific ingredients herein in amounts herein.

One of ordinary skill in the art would have been motivated to make the composition Claimed herein since a substantially similar composition is taught in the prior art. Morella et al. (USPN 5,378,474) teaches a similar composition which may contain an antihypertensive agent (including verapamil) and the excipients herein in amounts (wt. percentages) that overlap with those in the instant claims. The optimization of amounts of ingredients to be employed in a composition is considered within the skill of the artisan. The instant composition is not seen to patentably distinguish over the prior art, absent evidence to the contrary. No such evidence is

As to claims 26-50 reciting a intermediate coating which read on the same coating disclosed by Morella, note it would have been an obvious alternative for accomplish the coating

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by two steps instead of one step (i.e., coating two time with the same material). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The intermediate coating herein is construed as the same as the final coating. See, claims 30 and 46 herein which identify the intermediate coating comprising hydroxypropyl methylcellulose and polyethylene glycol. Both polymers are disclosed by Morella as part of the coating materials.

In response to appellant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., excluding the other polymer from the coating herein claimed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims herein use "comprising" and would read on any additional ingredients. The examiner does not see asserted "significant" difference between what disclosed in Morella and those herein claimed.

Appellants' arguments that the claimed invention shows a patentably distinct feature have been fully considered, but are found unpersuasive for following reasons:

1) the results shown in the declaration by Dr. Seth do not commensurate in scope of claimed invention. Particularly the results were obtained on a composition consisting of the polymer recited in the claims, wherein the claims use "comprising".

2) Appellants' own experiments showing the inferior of the cited references lack probative force. It is to be presumed also that skilled workers would as a matter of course, if they do not immediately obtain desired results, make certain experiments and adaptations, within

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the skill of the competent worker. "that it is not a difficult matter to carry out a process in such a fashion that it will not be successful and, therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight" In re Michalek, 74 USPQ 108, at 109 citing Bullard Company et al v. Coe, 147 F.2d. 568, 64 USPQ 359." One of skilled artisan, by reading Merolla's patent, would have understand the particular functions of each polymers employed in Merolla's examples, and "the dissolution rate of the soluble drug at various pH can be modified at will by altering the ratio of polymers." (Col. 9, lines 11-13 in Merolla et al).

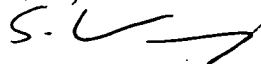
The examiner contends that claims 26-50 are not patentably distinct from claim 1 and therefore are obvious over Merolla et al. Particularly, the intermediate coating herein comprises hydroxylpropylcellulos and polyethylene glycol, and the specification provides no further definition as to the intermediate coating. Both hydroxylpropylcellulos and polyethylene glycol are disclosed by Merolla et al. as coating components. Therefore, the intermediate coating herein also read on the coating disclosed by Merolla et al. Therefore, the claims would read on multiple coating of the coating materials disclosed by Merolla et al. It would have been an obvious alternative to a skilled artisan for accomplishing the coating by two steps instead of one step (i.e., coating two time with the same material).

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,


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May 27, 2005

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